32. (CANCELLED).

33. (CURRENTLY AMENDED) The composition of claim 31, wherein the composition comprises, based on the total weight of dry ingredients, from about 85 to about 97.5 percent by weight guaifenesin, from about 1.0 to about 7 percent by weight polyvinylpyrrolidone binder, and from about 0.2 to about 4 percent by weight of solubilizer, or disintegrant, or solubilizer and disintegrant.

34. (PREVIOUSLY PRESENTED) The composition of claim 33, wherein the composition further comprises from about 0.1 to about 2 percent by weight of a glidant, and from about 0.1 to about 2 percent by weight of a lubricant.

35. (PREVIOUSLY PRESENTED) The composition of claim 31, wherein less than about 25 percent by weight of the particles exhibit a particle size of greater than about 425 micrometers, greater than about 85 percent by weight of the particles exhibit a particle size of greater than about 45 micrometers, and from about 17 to about 55 percent by weight of the particles exhibit a particle size of from greater than 45 micrometers to less than 150 micrometers.

36. (PREVIOUSLY PRESENTED) The composition of claim 31, wherein the composition exhibits a flow rate of greater than or equal to 6.5 grams per second, as measured using a VanKel flowmeter.

37. -38. (CANCELLED).

REMARKS

Claims 10, 30 and 37-38 have been cancelled.

Claims 1 and 31 have been amended to limit the claimed particles to an agglomerated mixture of guaifensin particles and a polyvinylpyrrolidone binder (support for

the amendment is provided at page 3, lines 17-19 and at page 6, lines 3-7 of the present application).

DENICK

Claims 6-8 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Denick.

The Examiner states in the *Final Rejection* that Denick discloses a particulate material that comprises both particles of guaifensin and magnesium aluminum silicate.

Applicant maintains that Denick does not disclose a particulate material that comprises particles of guaifenesin and particles magnesium aluminum silicate, i.e., the guaifenesin of Denick is sorbed onto the magnesium aluminum silicate particles and is thus not present in the form of discrete guaifenesin particles. As discussed in the *Amendment* of 12/30/2003, Denick discloses an adsorbate made by sorbing a solution of a medicament, such as an aqueous guaifenesin solution, onto a complex magnesium aluminum silicate sorbant to (see col. 1, line 42 to col. 2, line 8 of Denick).

Applicant's claims 6-8 each further limit Applicants amended claim 1 and thus each require particles that comprise an agglomerated mixture of guaifenesin particles and polyvinylpyrrolidone binder, as set forth in Applicant's amended claim 1.

Applicant further submits that the subject matter of Applicant's claims 6-8 would not have obvious at the time of the invention was made to a person having ordinary skill in the art in view of the disclosure of Denick, because the disclosure of Denick does not suggest Applicant's claimed particles that comprise an agglomerated mixture of guaifenesin particles and a polyvinylpyrrolidone binder.

For the reasons discussed above and those discussed in Applicant's *Amendment* dated 12/30/03, Applicant submits Applicant's claims 6-8 patentably distinguish over the

disclosure of Denick and therefore request that the Examiner reconsider and withdraw the rejection of claims 6-8 under 35 U.S.C. 103(a) as being unpatentable over Denick.

BLUME and MORSE

Claims 1-4, 6-10, 30, 31, and 33-38 stand finally rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,372,252 (Blume) in view of U.S. 4,269,859 (Morse).

Claims 10, 30, and 37-38 have been cancelled.

Blume discloses guaifensin compositions, but does not disclose a guaifenesin composition having the particle size distribution required by Applicant's claims. Morse is directed to a granular cellulosic binder having a specific particle size distribution. The Examiner urges that it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the cellulosic binder Morse in the guaifenesin containing composition of Blume.

The Examiner states in the *Final Rejection*, and suggests that Applicant has admitted, that Morse suggests that desired flow properties can be achieved using appropriate binder and other excipients, buy adjusting the level of excipients. Applicant maintains that the disclosure of Morse is not nearly so broad as is urged by the Examiner, i.e., as discussed in the *Amendment* of 12/30/2003:

- Morse recognizes that flow rate of a particulate mixture that comprises Morse's cellulose granules is impacted by the respective identities of the various components of such mixture and the relative amounts of such components, as well as by the particle size distribution of the mixture,
- Morse discloses that such cellulose granules are free flowing, that "in some cases" the cellulose granules may be advantageously admixed with pharmaceutical excipients and/or binders (see co 8, lines 45-49 of Morse), but that such pharmaceutical excipients, adjuvant or binders should not be employed at such levels as to reduce the desirable free flow characteristics of the cellulose granules (see col. 9, lines 5-12 of Morse), and

- Morse further cautions that this percentage admixture must be carefully considered because some commonly accepted excipients diminish the flow rate of the cellulose granules (col. 9, lines 5-18).

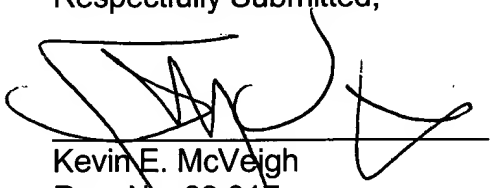
Applicant has limited the binder of Applicant's claims 1 and 31 to require a polyvinylpyrrolidone binder.

Applicant submits that the subject matter of Applicant's amended claims would not have obvious at the time of the invention was made to a person having ordinary skill in the art in view of the combined disclosures of Blume and Morse, because such disclosures provide no suggestion or guidance that would have would have led a person skilled in the art to, with any reasonable expectation of obtaining a flowable particulate mixture, extrapolate the disclosure of Morse beyond the cellulosic binder mixtures investigated by Morse in order to modify the composition of Blume in a manner consistent with the claimed particle size limitations for the particulate agglomerated mixture of guaifensin particles and polyvinylpyrrolidone binder of Applicant's amended claim 1.

For the reasons discussed above and those discussed in Applicant's *Amendment* dated 12/30/03, Applicant submits that Applicant's amended claims would patentably distinguish the present invention over the combined disclosure of Morse and Blume and therefore requests that the Examiner now reconsider and withdraw the rejection of claims 1-4, 6-9, and 31-36 of the present application under 35 U.S.C. 103(a) as being unpatentable over Blume in view of Morse.

For all the reasons discussed above, Applicant submits that as amended, claims 1-4, 6-9, and 31-36 of the present application patentably distinguish over the art of record and requests that the Examiner now allow those claims.

Respectfully Submitted,



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